UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA

LOLINE ROSSIGNOL BECKER and JOSEPH RAYMOND BECKER **Plaintiffs**	**CIVIL ACTION NO.** **COMPLAINT**
vs.	**JURY TRIAL DEMANDED**
DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON SERVICES, INC., and JOHNSON & JOHNSON **Defendants**	**SECTION** **MAGISTRATE**

COMPLAINT

NOW INTO COURT, comes Plaintiffs, Loline Rossignol Becker and Joseph Raymond Becker, who file this Complaint and allege the following upon information and belief:

BACKGROUND

1. This is an action to recover damages for personal injuries suffered by Plaintiffs, as a direct and proximate result of the Defendants', **DEPUY OTHROPAEDICS, INC., JOHNSON & JOHNSON SERVICES, INC., AND JOHNSON & JOHNSON, INC.**, negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, and/or sale of certain hip replacement devices, the ASR XL Acetabular System and the ASR Hip Resurfacing Platform (hereinafter collectively referred to as "Depuy ASR Hip Implant Devices" or "the Products(s)").

2. For more than two years, Defendants have known that the Depuy ASR Hip Implant Devices are prone to fail within approximately two years of implantation despite the fact that such hip implant devices are supposed to last more than fifteen years. They have also known that the implant's metal "ball" and "socket" bearings that make up the hip-joint generate metal debris over time from wear and tear that can spread throughout the patient's surrounding bone and tissue. As a result of these defects, patients that have had the devices implanted have endured, or will endure, unnecessary paid and suffering debilitating lack of mobility; inflammation causing damage or death to surrounding tissue and bone; and a subsequent more difficult revision surgery to replace the faulty devises giving rise to more debilitation, a prolonged recovery time, and an increased risk of complications and death from surgery. But rather than immediately recalling the Depuy ASR hip Implant Devices upon first receiving notice in 2008 of complaints made to the FDA of the defects discussed above, Defendants continued to aggressively market the Depuy ASR Hip Implant Devices, claiming that they were safe and effective hip replacement systems.

3. Plaintiffs' suffering could easily have been prevented. Plaintiff, Loline Rossignol Becker, would not have suffered from unnecessary pain and debilitation, and the possible need to undergo subsequent revision surgery had Defendants warned the public of the damages of the Depuy ASR Hip Implant Devices in 2007 when dozens of complaints began being made to the FDA regarding the devices' failures, or had Defendants taken the affirmative step of recalling the Depuy ASR Hip Implant Devices at that time, instead of more than three years later. But Defendants' recent recall of these devices has come too late for thousands of Americans, including Plaintiff, who will now live with the consequences of these faulty devices for years, if not the rest of their lives. Plaintiffs seek redress for their injuries.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000.00 exclusive of interest and costs. There is complete diversity of citizenship between the Plaintiffs and Defendants. Plaintiffs are residents of Gonzales, Louisiana, and Defendants are two New Jersey corporations, with their principal places of business in the State of New Jersey, and one Indiana corporation, with its principal place of business in the State of Indiana.

5. Venue is proper in this District pursuant to 28 U.D.C. § 1391(a), as Plaintiff obtained, purchased and had surgically implanted the Product, and suffered the injuries that form the basis of this lawsuit in this Federal District of Louisiana. Defendants all do substantial business in the State of Louisiana and within this Federal District, and at all times relevant hereto, Defendants developed, manufactures, promoted, marketed, distributed, tested, warranted and sold in interstate commerce the aforementioned Product.

PARTIES

6. Plaintiff, Loline Rossignol Becker, is a natural person and a resident of Ascension Parish, Louisiana.

7. Plaintiff, Raymond Joseph Becker, is the husband of Loline Rossignol Becker, and a natural person and resident of Ascension Parish, Louisiana.

8. Defendant, Depuy Orthopaedics, Inc. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. At all times material hereto, the Defendant, Depuy Orthopaedics, Inc., was engaged in the business of designing; developing, manufacturing, testing, packaging, promoting, marketing, distributing, and/or selling the Depuy ASR Hip

Implant Devices. Defendant, Depuy Orthopaedics, Inc., is and was at all times relevant herein doing business in and/or having directed its activities at Louisiana, and specifically this judicial district.

9. Defendant Johnson & Johnson Services, Inc. is, and at all times relevant to this Complaint was, a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all times material hereto, the Defendant, Johnson & Johnson Services, Inc., was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, and/or selling the Depuy ASR Hip Implant Devices. Defendant Johnson & Johnson Services, Inc. is and was at all times relevant herein doing business in and/or having directed its activities at Louisiana, and specifically this judicial district.

10. Defendant, Johnson & Johnson, is a New Jersey corporation having its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson has sufficient business contacts with the State of Louisiana to make it amenable to service of process, but does not maintain a regular place of business or a designated agent upon who service of process may be had for causes of action arising out of such business done in the State of Louisiana. For this reason, service of process sis to be made by serving the Secretary of State of Louisiana as agent and the Secretary of State is requested to forward a copy of the process with this Complaint to: **Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.** At all times material hereto, the Defendant, Johnson & Johnson, was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, and/or selling the Depuy ASR Hip Implant

Devices. Defendant, Johnson & Johnson, is and was at all times relevant herein doing business in and/or having directed its activities at Louisiana, and specifically this judicial district.

11. At all relevant times herein, the Depuy ASR Hip Implant Devices were designed, developed, manufactures, tested, packaged, promoted, distributed and/or sold by Defendants.

12. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendants.

FACTUAL ALLEGATIONS

13. Defendants' Depuy ASR Hip Implant Devices are prosthetic orthopaedic devices used in patients in need of hip replacement.

14. The Depuy ASR Hip Implant Devices were developed in order to reconstruct human hip joints that are diseased due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), or fracture. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

15. The ASR XL Axetabular System is made up of three components: the metal femoral stem in inserted inside the femur, the metal femoral head (or ball) connects to the stem and then fits inside the metal acetabulum cup (socket). The ASR Hip Resurfacing Platform has two components: a metal cap is placed over the natural femoral head (or ball) and the acetabulum is replaced with the metal acetabulum cup (socket). Once implanted, these devices are supposed to last for an average of about 15 or more years before requiring replacement.

16. On or about March 2010, Defendant Depuy issued a Field Safety Notice regarding its ASR hip replacement system. The Field Safety Notice provided new data which demonstrated that the ASR System had a higher than expected failure rate.

17. Depuy's recall notice stated that reasons for the higher than expected revisions of the metal-on-metal system included component loosening, component malalignment, infection, fracture of the bone, dislocation, metal sensitivity and pain.

18. In its nationwide recall, Depuy instructed physicians to cease implanting the device. Further, Depuy advised physicians to monitor the medical conditions of patients with the device through specific blood tests, radiographic tests and other diagnostic means. Further, Depuy advised physicians that revision surgery would be necessary in some cases, and that patients must receive revision surgery as soon as problems were detected in order to avoid further complications and injury.

Federal Requirements

19. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

20. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

21. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to

prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. § 360i.

22. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. 21 U.S.C. § 360j(f).

23. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 *et seq*. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods

and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

24. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

25. Pursuant to 21 CFR § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. See 21 CFR § 820.3(v).

26. Pursuant to 21 CFR 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

27. Pursuant to 21 CFR § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

28. Pursuant to 21 CFR § 820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

29. Pursuant to 21 CFR § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design and development.

30. Pursuant to 21 CFR § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

31. Pursuant to 21 CFR § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual simulated use conditions.

32. Pursuant to CFR § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

33. Pursuant to 21 CFR § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review and approval of design changes before their implementation.

34. Pursuant to 21 CFR § 820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

35. Pursuant to 21 CFR § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

36. Pursuant to 21 CFR § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

37. Pursuant to 21 CFR § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

38. Pursuant to 21 CFR § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

39. Pursuant to 21 CFR § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

40. Pursuant to 21 CFR § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

41. Pursuant to 21 CFR § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

42. Pursuant to 21 CFR § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation:" means establishing by objective evidence that a process consistently produces a result of product meeting its predetermined specifications. 21 CFR § 820.3(z)(1).

43. Pursuant to 21 CFR § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

44. Pursuant to 21 CFR § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

45. Pursuant to 21 CFR § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

Defendants' Depuy ASR Hip Implant Devices Are 510(k) Approved Medical Devices

46. Defendants submitted a § 510(k) premarket notification and obtained marketing approval for the Depuy ASR Hip Implant Devices from the FDA under Section 510(k) of the Act. See 21 U.S.C. § 360 *et seq*.

47. Under the § 510(k) approval process, the FDA determined that Defendants' Depuy ASR Hip Implant Devices were "substantially equivalent" to devices that have been

reclassified in accordance with the provisions of the Act and did not require FDA approval of a pre-market approval application (PMA).

48. Upon information and belief, Defendants' Depuy ASR Hip Implant Devices are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

49. Upon information and belief, Defendants' Depuy ASR Hip Implant Devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

50. Upon information and belief, Defendants' Depuy ASR Hip Implant Devices are adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain CGMP for their Depuy ASR Hip Implant Devices in accordance with 21 CFR § 820 *et seq.*, as set forth above.

51. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their Depuy ASR Hip Implant Devices.

52. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' Depuy ASR Hip Implant Devices are defective and failed, resulting in injuries to Plaintiff.

53. If Defendants had complied with the federal requirements regarding CGMP, Defendants' Depuy ASR Hip Implant Devices would have been manufactured properly such that it would not have resulted in injuries to Plaintiff.

Defendants Manufactured And marketed The Depuy ASR Hip Implant Devices To The Public, Even Though They Knew Or Should Have Known Of The Danger That The Depuy ASR Hip Implant Devices Posed To The Public

54. Defendants aggressively marketed the Depuy ASR Hip Replacement Devices as having many advantages over other hip replacement or hip resurfacing systems. Defendants described the Depuy ASR Hip Replacement Devices as a "high performance hip replacement" and advertised it with pictures of a young woman running on a sandy beach, and a man taking a very aggressive golf swing. Defendants advertised the Depuy ASR Hip Replacement Devices as superior devices as the bone in the hip socket was preserved, the hip replacement was subject to reduced wear, the hip replacement matched the hip's natural anatomy, the surgery only required a small incision, and the device was based on a strong clinical history.

55. Defendants further advertised the Depuy ASR Hip Replacement Devices as a superior option "[i]f you have gradually stopped doing the things you enjoy or are adapting your life to cope with reduced mobility, hip replacement surgery may be appropriate for you."

56. Contrary to Defendants' marketing campaigns, for more than two years Defendants have known that the Depuy ASR Hip Implant Devices were failing early and therefore causing harm in a high number of patients that received the devices. Specifically, for more than two years, the FDA has been receiving complaints that the devices failed early in some patients due to component loosening, component malalignment, dislocation, and fracture, due to the design of the devices. In addition, reports were received that the implant's "bail" and "socket" that make up the hip-joint – which are both metal bearings – generate metal debris over time from wear which can spread throughout the surrounding bone and tissue and cause severe inflammation and damage. Indeed, since the start of 2008, the FDA has received approximately 400 complaints involving patients in the United States that received the devices, with a

substantial number of these patients requiring complicated, expensive and painful revision surgeries with prolonged recovery time.

57. Notwithstanding these complaints, Defendants neither halted sales of the Depuy ASR Hip Implant Devices, nor warned the public until just recently. Instead, throughout 2008 and 2009 they aggressively marketed the Depuy ASR Hip Implant Devices as safe and effective hip replacement devices even though they were on notice of the high number of complaints received by the FDA. Only in the last quarter of 2009 did Defendants react by deciding to stop sales of the devices due to decreased demand.

58. However, faced with even more data regarding the dangers of ASR Hip Implant Devices, on August 24, 2010, Defendants took the extra step of issuing a voluntary recall of the Depuy ASR Hip Implant Devices after "new" data was released confirming the already known dangers of the devices, and corroborating the many complaints received by FDA from physicians and patients years earlier.

59. The data relied on for the recall includes British studies in March 2010 showing that metal-on-metal implants, such as the Depuy ASR Hip Implant Devices, are potentially dangerous because they can generate large amounts of metallic debris as they wear over time. The metallic debris has been shown to cause severe inflammatory responses in some patients that cause pain in the groin, and death of tissue in the hip joint and loss of surrounding bone, requiring a revision surgery to replace the device soon after implant instead of the 15 or more years artificial hips are supposed to last.

60. The other source is unpublished data from the National Joint Registry (NJR) of England and Wales. The NJR data shows the five year revision date for the ASR Hip Resurfacing System is approximately 12 percent, and is approximately 13 percent for the ASR

XL Acetabular System. Defendants acknowledge that under generally accepted standards, no more than 5 percent of patients should have a revision surgery within five years of implantation. The data released from the NJR shows that the Depuy ASR Hip Implant Devices had a revision rate almost three times that of the generally accepted standards.

61. Many surgeons have acknowledged that the culprit for the high number of revision surgeries is due to the design of the acetabulum metal cup which is shallower than other competitor's cups on the market. It is this shallower design which presents a challenge for properly implanting the device which can lead to problems such as loosening of the device, malalignment of the device, and fracture of the device from the bone, all of which can cause severe infection and inflammation in patients.

62. As a result of the issues with the Depuy ASR Hip Implant Devices, recipients have suffered symptoms including pain, swelling, inflammation and damage to surrounding bone and tissue, and partial or complete lack of mobility. As noted above, these symptoms are the result of possible loosening of the implant, where the implant does not stay attached to the bone in the correct position; fracture, where the bone around the implant may have broken; dislocation, where two parts of the implant that move against each other are no longer aligned; or the spread of metal debris from the metal femur head and metal acetabulum cup from rubbing and rotating against each other. For these reasons, revision surgeries have been necessary to remove the faulty Depuy ASR Hip Implant Device. However, these revision surgeries present enormous risks to patients because they are technically more difficult than the original implant surgery, the patient is more at risk of complications and death, and the recovery is more prolonged than the original hip replacement surgery.

As A Direct And Proximate Result Of Defendants' Failure To Recall The Hip Implant Devices Earlier, Plaintiff Received A Hip Implant Device, And Now Has Suffered Pain, Swelling, Decreased Mobility. And Potential Need For Revision Surgery

63. On or about August 29, 2007 Plaintiff, Loline Rossignol Becker, underwent left hip replacement surgery in which a Depuy ASR Hip Implant Device, was implanted in her body.

64. Since the surgical implantation of the Depuy ASR Hip Implant Device, Plaintiff, Loline Rossignol Becker, has suffered symptoms including, but not limited to pain, swelling, soreness, difficulty walking, and decreased mobility.

65. Had Plaintiff known that the Depuy ASR Hip Implant Device caused pain, swelling, inflammation and damage to surrounding bone and tissue as well as a partial or complete lack of mobility, and the potential need for revision surgery to explant the device, Plaintiff would not have elected to have had the Depuy ASR Hip Implant Device implanted.

66. As a direct and proximate result of the implantation of Depuy ASR Hip Implant Device, Plaintiff has suffered significant harm, including but not limited to physical injury and bodily impairment, debilitating lack of mobility and conscious pain and suffering.

67. On or about December 16, 2010, Plaintiff, Loline Rossignol Becker, received a notice from Defendants, through a third party company named Broadspire, that the hip replacement implant she received on or around August 29, 2007, had been recalled by Depuy.

68. As a direct and proximate result of Defendants' defective Depuy ASR Hip Implant Device, Plaintiff, Loline Rossignol Becker, will have to undergo radiographic evaluation, blood testing, and an MRI.

69. As a direct and proximate result of Defendants' defective Depuy ASR Hip Implant Device, Plaintiff, Loline Rossignol Becker, will likely have to undergo another surgery

to remove and replace the defective Depuy ASR Hip Implant Device.

70. As a direct and proximate result of Defendants' defective Depuy ASR Hip Implant Device, Plaintiff, Loline Rossignol Becker, has suffered significant harm, conscious pain and suffering, physical injury, bodily impairment, mental anguish and emotional distress.

71. As a direct and proximate result of Defendants' defective hip replacement implant, Plaintiff has also incurred medical expenses and other economic harm, and will continue to incur such expenses and other economic harm in the future.

72. Plaintiff, Joseph Raymond Becker, at all times relevant herein was married and continues to be married to Loline Rossignol Becker and therefore sustained a loss of consortium as a result of the incident sued upon herein, all of which entitles him to recover damages as are reasonable in the premises.

73. At all times material hereto, Defendants, by and through their agents, servants and/or employees, failed to adequately warn physicians and consumers, including Plaintiff, of the risks of the Depuy ASR Hip Implant Devices.

74. At all times material hereto, Defendants, by and through their agents, servants and/or employees, negligently, recklessly and/or carelessly marketed, distributed and/or sold the Depuy ASR Hip Implant Devices without adequate instructions or warnings of their serious side effects and unreasonably dangerous risks.

75. At all times material hereto, the Defendants failed to comply or properly comply with Federal law in connection with the Depuy ASR Hip Implant Devices.

76. At all times material hereto, Defendants either knew or should have known that the Depuy ASR Hip Implant Devices was causally related to and associated with severe complications and side effects.

77. Although Defendants knew or should have known that dangerous risks were associated with the use of the Depuy ASR Hip Implant Devices, Defendants proceeded to or permitted the Depuy ASR Hip Implant Devices to be advertised, promoted and/or sold without adequate warnings of the serious side effects and dangerous risks.

78. Defendants breached obligations associated with the Depuy ASR Hip Implant Devices including, but not limited to, their testing, the manufacture, design, warning, marketing, and sale.

79. Defendants expressly warranted to the market, including Plaintiff, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, advertisements and other materials to the health care and general community, that the Depuy ASR Hip Implant Devices were safe, effective, fit and proper for its intended use.

80. In using the Depuy ASR Hip Implant Devices, Plaintiff Loline Rossignol Becker and her physicians relied on the skill, judgment, representations, and foregoing express warranties of the Defendants. These warranties and representations proved to be false because the product was not safe and was unfit for the uses for which it was intended.

81. As a direct and proximate result of Defendants' breaches of warranties, Plaintiffs were injured and suffered damages.

82. Defendants have breached the implied warranty of merchantability in that but failed to fully disclose were not reasonably fit for the purposes, for which it was sold, intended, or reasonably foreseen, to be used. Moreover, the Depuy ASR Hip Implant Devices manufactured and sold by Defendants were defective on the date of delivery to Plaintiff.

83. Defendants have also breached the implied warranty of fitness for a particular

purpose. The Depuy ASR Hip Implant Devices are not reasonably fit for the specific purposes for which Defendants knowingly sold it and for which Plaintiffs bought it, in reliance on Defendants.

84. Plaintiff has suffered damages as a result of Defendants' breach of warranty.

85. Defendants have a duty to exercise the necessary degree of care expected and required of manufacturers of health care products. Defendants deviated from that duty by failing to warn of the risks in using the Depuy ASR Hip Implant Devices.

86. Defendants failed to adequately warn Plaintiff of the hazards of the Depuy ASR Hip Implant Devices and concealed this knowledge from Plaintiff and others. As a result of this failure, Plaintiff was caused to suffer the injuries and damages as set forth herein.

87. Defendants falsely misrepresented and concealed pertinent facts regarding the Depuy ASR Hip Implant Devices including, without limitation, the absence of adequate testing, the. lack of proper manufacturing practices, the severity and frequency of side effects, and adverse medical conditions caused by the Depuy ASR Hip Implant Devices.

88. Defendants failed to take measures to ensure that the recipients of the Depuy ASR Hip Implant Devices were notified fully and completely of the risks of the Depuy ASR Hip Implant Devices, and/or those physicians, pharmacists and health care providers were notified of these risks.

89. The Defendants failed to adequately warn consumers of the harmful side effects and potential adverse health effects of the Depuy ASR Hip Implant Devices. The Depuy ASR 1-lip Implant Devices were dangerous and defective at the time they were marketed by Defendants, and at the time they were surgically implanted into Plaintiff, Loline Rossignol Becker.

90. The dangerous and defective conditions of the Depuy ASR Hip Implant Devices proximately caused the injuries Plaintiffs allege herein, all while the product was used for its ordinary intended purpose and in the ordinary intended manner. The injuries alleged here by Plaintiffs, and damages suffered were the direct and proximate result of the marketing and sale by Defendants of the defective and unreasonably dangerous the Depuy ASR Hip Implant Devices.

91. Defendants failed to properly and adequately test the Depuy ASR Hip Implant Devices.

92. As a result of her use of the Depuy ASR Hip Implant Devices, Plaintiff, Loline Rossignol Becker, has sustained the following non-exclusive list of damages:

a. Physical injuries;

b. Past and future emotional distress;

c. Loss of enjoyment of life;

d. Past and future mental pain and suffering;

e. Inconvenience;

f. Past and future physical pain, suffering and disability;

g. Past and future medical expenses;

h. Other damages to be proven at the trial of this matter.

93. Plaintiff, Joseph Raymond Becker, at all times relevant herein was married and continues to be married to Loline Rossignol Becker and therefore sustained a loss of consortium as a result of the incident sued upon herein, all of which entitles him to recover damages as are reasonable in the premises.

FRAUDULENT CONCEALMENT

94. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true risks associated with the Depuy ASR Hip Implant Devices

95. As a result of Defendants' actions, Plaintiff Loline Rossignol Becker and her physicians were unaware, and could not reasonably have known or have learned through reasonable diligence that she had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

COUNT ONE

LOUISIANA PRODUCTS LIABILITY ACT

96. Plaintiffs hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

97. The Depuy ASR Hip Implant Devices proximately caused damage to the Plaintiff, which damage was caused by a characteristic of the product that rendered it unreasonably dangerous arising from a reasonably anticipated use of the product by Plaintiff, thus rendering Defendants liable to Plaintiff pursuant to LSA R.S. 9:2800.54.

98. The Depuy ASR Hip Implant Devices are unreasonably dangerous for the following reasons:

a. They are unreasonably dangerous in construction or composition as provided in LSA R.S. 9:2800.55;

b. They are unreasonably dangerous in design as provided in LSA R.S. 9:2800.56.

c. They are unreasonably dangerous because an accurate warning about the product was not provided as required by LSA R.S. 9:2800.57.

d. They are unreasonably dangerous because they do not conform to an express warranty of the manufacturer about the product as provided in LSA R.S. 9:2800.58.

99. The characteristics of the product that render it unreasonably dangerous under LSA R.S. 9:2800.55, LSA R.S. 9:2800.56, and LSA R.S. 9:2800.57 *et seq.* existed at the time the product left the control of the manufacturer or resulted from a reasonably anticipated alteration or modification of the product.

100. The Depuy ASR Hip Implant Devices manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in their manufacture and construction when they left the hands of Defendants in that they deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

101. As a direct and proximate result of Plaintiff's use of the Depuy ASR Hip Implant Devices, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

102. For all of the reasons alleged herein, the Depuy ASR Hip Implant Devices were unreasonably dangerous in design at the time the product left the manufacturer's control in that:

a. There existed an alternate design for the product that was capable of preventing

the Plaintiff's damages; and

b. The likelihood that the product's design would cause the Plaintiff's damages and the gravity of those damages outweigh the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

103. For all of the reasons alleged herein, the Depuy ASR Hip Implant Devices are unreasonably dangerous because an adequate warning about the product had not been provided and at the time the product left the manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide adequate warning that such characteristic and its dangers to users of the product.

104. Further, Defendants, after the product left their control, acquired knowledge of the characteristic of the product that may cause damage and the danger of such characteristic (or, alternatively, Defendants would have acquired such knowledge if they had acted as reasonable prudent manufacturers), and thus are liable for damages suffered by Plaintiff which arose as a consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its dangers to users.

105. Defendants expressly warranted to the market, including Plaintiff, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, advertisements and other materials to the health care and general community, that the Depuy ASR Hip Implant Devices were safe, effective, fit and proper for its intended use.

106. In using the Depuy ASR Hip Implant Devices, Plaintiff and her physicians relied on the skill, judgment, representations, and foregoing express warranties of the

Defendants. These warranties and representations proved to be false because the product was not safe and was unfit for the uses for which it was intended.

COUNT TWO

VIOLATION OF WARRANTY OF REDHIBITION

107. Plaintiffs hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

108. Defendants were aware of the substantial risks from using the Depuy ASR Hip Implant Devices but failed to fully disclose the same.

109. Defendants, as the manufacturer of the Depuy ASR Hip Implant Devices, are deemed to be aware of its redhibitory defects pursuant to LSA-C.C. Article 2545.

110. Had Plaintiff been aware of the defects contained in the Depuy ASR Hip Implant Devices, Plaintiff would not have purchased the Depuy ASR Hip Implant Devices. This characteristic rendered it unfit for its intended purposes.

111. Defendants are liable unto Plaintiff under the theory of redhibition as a consequence of the sale to Plaintiff of a product unfit for its intended use.

112. Plaintiff is entitled to return of any purchase price paid, including but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys fees and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which Plaintiffs may be entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays:

a. That process issue according to law;

b. that each Defendant be served with a copy of Plaintiffs' Complaint and show cause why the prayers for relief requested by Plaintiffs should not be granted;

c. that Plaintiffs be granted a trial by jury in this matter;

d. that the Court enter judgment against each Defendant, jointly and severally, for all general and compensatory damages allowable to Plaintiffs;

e. that the Court enter judgment against each Defendant, jointly and severally, for all hedonic damages allowable to Plaintiffs;

f. that the Court enter judgment against each Defendant, jointly and severally, for all other special damages allowable to Plaintiffs;

g. that the Court enter judgment against each Defendant, jointly and severally, for all other relief sought by Plaintiffs under this Complaint;

h. that the Court render judgment in favor of the Plaintiffs, awarding all damages as prayed for herein, including attorneys' fees, with all costs assessed against Defendant; and

i. that the Court grant Plaintiff such other and further relief to which the Court deems just and appropriate.

JURY DEMAND

Pursuant to the Federal Rule of Civil Procedure 38(b), Plaintiff demands trial by jury on all issues so triable.

Dated: March 9, 2011

Respectfully submitted,

THE LAW OFFICE OF
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